Complete Summary

GUIDELINE TITLE

Post-traumatic stress disorder. The management of PTSD in adults and children in primary and secondary care.

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Mental Health. Post-traumatic stress disorder: the management of PTSD in adults and children in primary and secondary care. London (UK): National Institute for Clinical Excellence (NICE); 2005. 167 p. [69 references]

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- On May 12, 2006, GlaxoSmithKline (GSK) and the U.S. Food and Drug Administration (FDA) notified healthcare professionals of changes to the Clinical Worsening and Suicide Risk subsection of the WARNINGS section in the prescribing Information for Paxil and Paxil CR. These labeling changes relate to adult patients, particularly those who are younger adults.

  A recent meta-analysis conducted of suicidal behavior and ideation in placebo-controlled clinical trials of paroxetine in adult patients with psychiatric disorders including Major Depressive Disorder (MDD), other depression and non-depression disorders. Results of this analysis showed a higher frequency of suicidal behavior in young adults treated with paroxetine compared with placebo. Further, in the analysis of adults with MDD (all ages), the frequency of suicidal behavior was higher in patients treated with paroxetine compared with placebo. This difference was statistically significant; however, as the absolute number and incidence of events are small, these data should be interpreted with caution. All of the reported events of suicidal behavior in the adult patients with MDD were non-fatal suicide attempts, and the majority of these attempts (8 of 11) were in younger adults aged 18-30. These MDD data suggest that the higher frequency observed in the younger adult population across psychiatric disorders may extend beyond the age of 24.

It is important that all patients, especially young adults and those who are improving, receive careful monitoring during paroxetine therapy regardless of the condition being treated. See the FDA Web site for more information.

- On December 8, 2005, the U.S. Food and Drug Administration (FDA) has determined that exposure to paroxetine in the first trimester of pregnancy may increase the risk for congenital malformations, particularly cardiac malformations. At the FDA's request, the manufacturer has changed paroxetine's pregnancy category from C to D and added new data and recommendations to the WARNINGS section of paroxetine's prescribing information. FDA is awaiting the final results of the recent studies and accruing additional data related to the use of paroxetine in pregnancy in order to better characterize the risk for congenital malformations associated with paroxetine.

  Physicians who are caring for women receiving paroxetine should alert them to the potential risk to the fetus if they plan to become pregnant or are currently in their first trimester of pregnancy. Discontinuing paroxetine therapy should be considered for these patients. Women who are pregnant, or planning a pregnancy, and currently taking paroxetine should consult with their physician about whether to continue taking it. Women should not stop the drug without discussing the best way to do that with their physician. See the FDA Web site for more information.

- On September 27, 2005, GlaxoSmithKline (GSK) and the U.S. Food and Drug Administration (FDA) notified healthcare professionals of changes to the Pregnancy/PRECAUTIONS section of the Prescribing Information for Paxil and Paxil CR Controlled-Release Tablets to describe the results of a GSK retrospective epidemiologic study of major congenital malformations in infants born to women taking antidepressants during the first trimester of pregnancy. This study suggested an increase in the risk of overall major congenital malformations for paroxetine as compared to other antidepressants [OR 2.2; 95% confidence interval, 1.34-3.63]. Healthcare professionals are advised to carefully weigh the potential risks and benefits of using paroxetine therapy in women during pregnancy and to discuss these findings as well as treatment alternatives with their patients. See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Post-traumatic stress disorder (PTSD)

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Prevention
Screening
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Pediatrics
Psychiatry
Psychology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Emergency Medical Technicians/Paramedics
Hospitals
Nurses
Occupational Therapists
Patients
Physicians
Psychologists/Non-physician Behavioral Health Clinicians
Social Workers

GUIDELINE OBJECTIVE(S)

To make recommendations and suggest good practice points for the treatment and management of post-traumatic stress disorder (PTSD). Specifically, the guideline aims to:

- Evaluate the role of specific psychological interventions in the treatment and management of PTSD
- Evaluate the role of specific pharmacological interventions in the treatment and management of PTSD
- Evaluate the role of early psychological and pharmacological interventions shortly after traumatic event
- Address the issues of diagnosis, detection and the use of screening techniques in high-risk situations

- Provide key review criteria for audit, which will enable objective measurements to be made of the extent and nature of local implementation of this guidance, particularly its impact upon practice and outcomes for people with PTSD.

TARGET POPULATION

Adults and children of all ages, who meet the diagnostic criteria for, or are at risk for, post-traumatic stress disorder (PTSD)

INTERVENTIONS AND PRACTICES CONSIDERED

Screening and Diagnosis of Post-Traumatic Stress Disorder (PTSD)

1. Symptom assessment and coordination of care (including determination of need for emergency or psychiatric assessment)
2. Screening of individuals involved in major disasters, refugees, and asylum seekers
3. Assessment of comorbid conditions
4. Familiarisation with ethnic and cultural background of patient
5. Special considerations for assessing PTSD symptoms in children

Psychological Interventions

1. Trauma-focused cognitive behavioural therapy
2. Eye movement desensitisation and reprocessing (EMDR)

Pharmacologic Therapy

1. Antidepressants
    - Mirtazapine
2. Selective serotonin reuptake inhibitors
    - Paroxetine
3. Tricyclic antidepressants
    - Amitriptyline
4. Monoamine oxidase inhibitors
    - Phenelzine
5. Hypnotic medication
6. Antipsychotic agents
    - Olanzapine
7. Management of side effects of therapy and discontinuation/withdrawal symptoms

Other Practices

1. Watchful waiting

Supportive Measures

1. Family and carer support
2. Disaster planning (organization of social and psychological support)

Interventions Considered But Not Recommended

Sertraline, fluoxetine, imipramine, venlafaxine, risperidone relaxation therapy, hypnotherapy, supportive therapy, non-directive therapy, systemic psychotherapy and psychodynamic therapy, debriefing, repetitive transcranial magnetic stimulation (rTMS).

MAJOR OUTCOMES CONSIDERED

- Incidence and prevalence of post-traumatic stress disorder (PTSD)
- Symptom improvement (as measured by independent assessors or self-report)
- Side effects of pharmacologic therapy
- Relapse rate
- Impact on patient carers

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A stepwise, hierarchical approach was taken to locating and presenting evidence to the Group. The National Collaborating Centre for Mental Health (NCCMH) developed this process based on advice from the National Institute for Health and Clinical Excellence (NICE) National Guidelines Support and Research Unit and after considering recommendations from a range of other sources. These included:

- The Centre for Clinical Policy and Practice of the New South Wales Health Department (Australia)
- Clinical Evidence Online
- Cochrane Collaboration
- New Zealand Guideline Group
- National Health Service (NHS) Centre for Reviews and Dissemination
- Oxford Centre for Evidence-Based Medicine
- Scottish Intercollegiate Guidelines Network
- United States Agency for Health Research and Quality
- Oxford Systematic Review Development Programme

The Review Process

A brief search of the major bibliographic databases for recent systematic reviews and existing guidelines was first conducted to help inform the development of the scope. After the scope was finalised, a more extensive search for systematic reviews was undertaken. At this point, the review team, in conjunction with the Group, developed an evidence map that detailed all comparisons necessary to

answer the clinical questions. The initial approach taken to locating primary-level studies depended on the type of clinical question and availability of evidence.

After consulting the Group, the review team decided which questions were likely to have a good evidence base and which questions were likely to have little or no directly relevant evidence. For questions in the latter category, a brief descriptive review was initially undertaken by a member of the Group. For questions with a good evidence base, the review process depended on the type of clinical question.

Search Process for Questions Concerning Interventions

For questions related to interventions, the initial evidence base was formed from well-conducted randomised controlled trials (RCTs) that addressed at least one of the clinical questions. Although there are a number of difficulties with the use of RCTs in the evaluation of interventions in mental health, the RCT remains the most important method for establishing treatment efficacy.

The initial search for RCTs involved searching the standard mental health bibliographic databases (EMBASE, Medline, PsycINFO, Cochrane Library) for all RCTs potentially relevant to the guideline.

After the initial search results were scanned liberally to exclude irrelevant papers, the review team used a purpose-built 'study information' database to manage both the included and the excluded studies (eligibility criteria were developed after consultation with the Group). For questions without good-quality evidence (after the initial search), a decision was made by the Group about whether to repeat the search using subject-specific databases, such as CINAHL, the Allied and Complementary Medicine Database (AMED), the System for Information on Grey Literature in Europe (SIGLE) and the Publishers International Literature on Traumatic Stress (PILOTS); conduct a new search for lower levels of evidence; or adopt a consensus process (see section of the original guideline document entitled Primary Care Focus Group). Future guidelines will be able to update and extend the usable evidence base starting from the evidence collected, synthesised and analysed for this guideline.

Data from unpublished pharmacological trials held by the Medical and Healthcare Products Regulatory Agency were routinely requested, and where these data were available and could be released they are considered within the review.

Recent high-quality English-language systematic reviews were used primarily as a source of RCTs (see Appendix 7 of original guideline document for quality criteria). However, where existing data-sets were available from appropriate reviews, they were cross-checked for accuracy before use.

New RCTs meeting inclusion criteria set by the Group were incorporated into the existing reviews and fresh analyses performed. The review process is illustrated in the Figure in the original guideline document entitled "Guideline Review Process".

Additional searches were made of the reference lists of all eligible systematic reviews and RCTs, and the list of evidence submitted by stakeholders. Known experts in the field (see Appendix 2 of original guideline document), based both

on the references identified in early steps and on advice from Group members, were sent letters requesting systematic reviews or RCTs that were in the process of being published (unpublished full trial reports were also accepted where sufficient information was available to judge eligibility and quality). In addition, the standard mental health bibliographic databases were periodically checked for relevant studies.

Search Process for Questions of Screening and Risk Factors

For questions related to screening and risk factors, the search process was the same as described above, except that the initial evidence base was formed by identifying recent high-quality systematic reviews and updating the searches for these systematic reviews. Additional searches were run to cover aspects of screening and risk factors that the Group felt had not been comprehensively covered by these earlier systematic reviews. (Separate searches were run for screening tools and risk factors of injury, compensation and litigation, and all studies of risk factors with a longitudinal prospective design.) In situations in which it was not possible to identify a substantial body of appropriately designed studies that directly addressed each clinical question, a consensus process was adopted (see the original guideline document for details).

Search Filters

Search filters developed by the review team consisted of a combination of subject heading and free-text phrases. Specific filters were developed for the guideline topic, and where necessary, for each clinical question. In addition, the review team used filters developed for systematic reviews, RCTs and other appropriate research designs (Appendix 6 of original guideline document).

Study Selection

All primary-level studies included after the first scan of citations were acquired in full and reevaluated for eligibility at the time they were being entered into the study information database. The inclusion criteria for RCTs are listed below. For certain clinical questions these inclusion criteria were amended (see Chapter 9 of original guideline document). All eligible papers were then critically appraised for methodological quality (see Appendix 8 of original guideline document). The eligibility of each study was confirmed by at least one member of the Group.

For some clinical questions, it was necessary to prioritise the evidence with respect to the UK context. To make this process explicit, the Group took into account the following factors when assessing the evidence:

- participant factors (e.g. gender, age, ethnicity)
- provider factors (e.g. model fidelity, the conditions under which the intervention was performed, the availability of experienced staff to undertake the procedure)
- cultural factors (e.g. differences in standard care, differences in the welfare system).

The Group decided which prioritisation factors were relevant to each clinical question in light of the UK context, and then how they should modify the recommendations.

Inclusion Criteria

The review used the following inclusion criteria:

- the study used a randomised controlled design
- at least 70% of participants needed to have a diagnosis of PTSD, other participants must have PTSD symptoms following a traumatic event
- the main target of treatment was PTSD
- PTSD symptoms were measured pre- and post-treatment data were reported for continuous data at least 50% of the intent-to-treat sample were assessed at the relevant time point
- double-blind administration of treatment (for pharmacological treatments only).

Health Economics Review Search Strategy

In January 2004, bibliographic electronic databases -- Medline, PreMedline, EMBASE, CINAHL, PsycINFO, the Cochrane Database of Systematic Reviews (CDSR), Cochrane Controlled Trials Reports (CCTR), Database of Abstracts of Reviews of Effectiveness (DARE) and the NHS Health Technology Assessment (HTA) -- and specific health economic databases, the NHS Economic Evaluation Database (NHS EED) and the Office of Health Economics Health Economic Evaluation Database (OHE HEED), were searched for economic studies. For Medline, PreMedline, EMBASE, CINAHL, PsycINFO, CDSR, CCTR and DARE, a combination of a specially developed health economics search filter already tested in earlier NCCMH guidelines and a general filter for post-traumatic stress disorder was used. A combination of subject headings and free-text searches was used. The HTA, NHS EED and OHE HEED databases were searched using shorter, database-specific strategies.

In addition to searches of electronic databases, reference lists of eligible studies and relevant reviews were searched by hand. Studies included in the clinical evidence review were also screened for economic evidence.

Review Process

The database searches for general health economic evidence for PTSD resulted in a total of 345 references. Of these, 27 were identified as potentially relevant. Secondary searches for additional pharmaco-economic papers resulted in a further 46 references, of which 8 were initially considered relevant to criteria for health economic appraisal. A further 6 potentially eligible references were found by hand-searching. Full texts of all potentially eligible studies (including those for which relevance or eligibility was not clear from the abstract) were obtained: a total of 41 papers. (At this stage inclusion was not limited to papers only from the UK.) These publications were then assessed against a set of standard inclusion criteria by the health economist, and papers eligible for inclusion as economic evaluations were subsequently assessed for internal validity. The quality assessment was based on the 32-point checklist used by the British Medical

Journal to assist referees in appraising economic analyses (see Appendix 12 of original guideline document).

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

I: Evidence obtained from a single randomised controlled trial or a meta-analysis of randomised controlled trials

IIa: Evidence obtained from at least one well-designed controlled study without randomisation

IIb: Evidence obtained from at least one other well-designed quasi-experimental study

III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, and case studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities.

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Synthesising the Evidence

Where possible, outcome data were extracted directly from all eligible studies, which met the quality criteria, into Review Manager 4.2. Meta-analysis was then used, where appropriate, to synthesise the evidence using Review Manager. If necessary, reanalyses of the data or sensitivity analyses were used to answer clinical questions not addressed in the original studies or reviews. For continuous outcomes, where more than 50% of the total number randomised in a particular study were not accounted for, the data were excluded from the analysis because of the risk of bias.

Included/excluded studies tables, generated automatically from the study information database, were used to summarise general information about each study (see Appendix 14 of original guideline document). Where meta-analysis was

not appropriate and/or possible, the reported results from each primary-level study were also presented in the included studies table.

Consultation was used to overcome difficulties with coding. Data from studies included in existing systematic reviews were extracted independently by one reviewer directly into Review Manager and cross-checked with the existing data-set. Two independent reviewers extracted data from new studies, and disagreements were resolved with discussion. Where consensus could not be reached, a third reviewer resolved the disagreement. Masked assessment (i.e., masked to the journal from which the paper came, the authors, the institution and the magnitude of the effect) was not used, since it is unclear that doing so reduces bias.

Presenting the Data to the Guideline Development Group

Where possible, meta-analysis was used to synthesise data. If necessary, sub-analyses were used to answer clinical questions not addressed in the original studies or reviews. The Group was given a graphical presentation of the results using forest plots generated with the Review Manager software. Each forest plot displayed the effect size and confidence interval (CI) for each study as well as the overall summary statistic. The graphs were organised so that the display of data in the area to the left of the 'line of no effect' indicated a 'favourable' outcome for the treatment in question. Dichotomous outcomes were presented as relative risks (RR) with the associated 95% CI. A relative risk (or risk ratio) is the ratio of the treatment event rate to the control event rate. An RR of 1 indicates no difference between treatment and control. If the CI does not cross the 'line of no effect', the effect is statistically significant.

All dichotomous outcomes were calculated on an intention-to-treat basis (i.e., a 'once randomized always analyse' basis). This assumes that participants who ceased to engage in the study -- from whatever group -- had an unfavourable outcome (with the exception of the outcomes of death and certain adverse events). Continuous outcomes were analysed as standardised mean differences (SMDs) to allow for ease of comparison across studies. If provided, intention-to-treat data, using a method such as 'last observation carried forward', were preferred over data from completers.

To check for heterogeneity between studies, both the I^2 and Chi^2 tests of heterogeneity ($P<0.10$), as well as visual inspection of the forest plots, were used. The I^2 statistic describes the proportion of total variation in study estimates that is due to heterogeneity. An I^2 of less than 30% was taken to indicate mild heterogeneity and a fixed effects model was used to synthesise the results. An I^2 of more than 50% was taken as notable heterogeneity. In this case, an attempt was made to explain the variation. If studies with heterogeneous results were found to be comparable, a random effects model was used to summarise the results. In the random effects analysis, heterogeneity is accounted for both in the width of CIs and in the estimate of the treatment effect. With decreasing heterogeneity the random effects approach moves asymptotically towards a fixed effects model. An I^2 of 30-50% was taken to indicate moderate heterogeneity. In this case, both the Chi^2 test of heterogeneity and a visual inspection of the forest plot were used to decide between a fixed and random effects model.

Developing Statements

For each outcome a clinical statement describing the evidence found was developed. To assess clinical importance where a statistically significant summary was obtained (after controlling for heterogeneity) the Group set thresholds for determining clinical importance, in addition to taking into account the trial population and nature of the outcome.

Two separate thresholds for determining clinical importance were set. For comparisons of one active treatment against waiting list or non-active interventions, a higher threshold was applied than for comparisons of active treatments against one another.

For comparisons of one active treatment against another treatment the following thresholds were applied: for dichotomous outcomes an RR of 0.80 or less was considered clinically important and for continuous outcomes an effect size of approximately 0.5 (a 'medium' effect size) or less was considered clinically important.

For comparisons of active treatment against waiting list the following thresholds were applied: for dichotomous outcomes a RR of 0.65 or less was considered clinically important and for continuous outcomes an effect size of approximately 0.8 (a 'large' effect size) or less was considered clinically important.

In order to facilitate consistency in generating and drafting the clinical statements the Group used a statement decision tree. This flow chart was designed to assist with decision making, not to replace clinical judgement. Using this procedure, the Group classified each effect size as clinically important or not (i.e., whether or not the treatment is likely to benefit PTSD sufferers), taking into account both the comparison group and the outcome.

Where heterogeneity between studies was judged problematic, in the first instance an attempt was made to explain the cause of the heterogeneity (e.g., outliers were removed from the analysis, or sub-analyses were conducted to examine the possibility of moderators). Where homogeneity could not be achieved, a random effects model was used.

In cases where the point estimate of the effect was judged clinically important, a further consideration was made about the precision of the evidence by examining the range of estimates defined by the CI. For level I evidence, where the effect size was judged clinically important for the full range of plausible estimates, the result was described as evidence favouring intervention x over intervention y (i.e., statement 1, or S1). For non-level-I evidence or in situations where the point estimate was clinically important but the CI included clinically unimportant effects, the result was described as limited evidence favouring intervention x over intervention y (i.e., S2). Where a point estimate was judged as not clinically important and the CI did not include any clinically important effects, the result was described as unlikely to be clinically important (i.e., S3). Alternatively, if the range of estimates defined by the CI included clinically important benefits as well as no effect or harmful effects, the result was described as inconclusive (i.e., S4).

Where for a particular review very few trials meet the threshold for clinical importance, further criteria are required to differentiate the relative efficacy of treatments considered. In this case treatments are evaluated according to whether they are both statistically significant and reasonably well tolerated. Specifically, the most effective treatments are identified as those for which, for the principal outcome measures, the effect sizes are statistically significant (95% CI to the left of the line of no effect).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus
Informal Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Guideline Development Group

The Guideline Development Group consisted of professionals in psychiatry, clinical psychology, nursing, social work and general practice; academic experts in psychiatry and psychology; and post-traumatic stress disorder (PTSD) sufferers. The guideline development process was supported by staff from the National Collaborating Centre for Mental Health (NCCMH), who undertook the clinical and health economics literature searches, reviewed and presented the evidence to the Group, managed the process, and contributed to the drafting of the guideline.

Guideline Development Group Meetings

Seventeen Group meetings were held between February 2003 and June 2004. During each daylong meeting, in a plenary session, clinical questions and clinical evidence were reviewed and assessed, statements developed and recommendations formulated. At each meeting all Group members declared any potential conflict of interest, and PTSD sufferer and carer concerns were routinely discussed as part of a standing agenda.

Topic Leads

The Group divided its workload along clinically relevant lines to simplify the guideline development process, and individual members took responsibility for advising on guideline work for particular areas of clinical practice (psychological interventions, pharmacological interventions, early intervention, risk factors and screening, and children).

PTSD Sufferers and Carers

Individuals with direct experience of services gave an integral PTSD sufferer focus to the Group and to the guideline. The Group included two PTSD sufferers, both of whom had contact with other PTSD sufferers and carers. They contributed as full Group members to writing the clinical questions, helping to ensure that the evidence addressed their views and preferences, highlighting sensitive issues and terminology associated with PTSD, and bringing PTSD sufferer research to the

attention of the Group. In drafting the guideline, they contributed to the editing of the introduction and Chapter 3 (Experiences of PTSD Sufferers and Carers) of the original guideline document, and identified good practice points from the PTSD sufferer and carer perspectives.

Special Advisers

Special advisers who had specific expertise in one or more aspects of treatment and management relevant to the guideline assisted the Group, commenting on specific aspects of the developing guideline and making presentations to the Group. The Acknowledgements section at the beginning of this guideline lists those who agreed to act as special advisers.

National and International Experts

National and international experts in the area under review were identified through the literature search and through the experience of the Group members. These experts were contacted to recommend unpublished or soon-to-be published studies in order to ensure up-to-date evidence was included in the development of the guideline. They informed the group about completed trials at the pre-publication stage, systematic reviews in the process of being published, studies relating to the cost-effectiveness of treatment, and trial data if the Group could be provided with full access to the complete trial report. Appendix 4 of the original guideline document lists the researchers who were contacted.

Developing and Grading the Recommendations

Once all evidence statements relating to a particular clinical question were finalised and agreed by the Group, the associated recommendations were produced and graded. Grading allowed the Group to distinguish between the level of evidence and the strength of the associated recommendation. This allowed the Group to moderate recommendations based on factors other than the strength of evidence. Such considerations include the applicability of the evidence to the people in question, economic considerations, values of the development group and society, and the group's awareness of practical issues.

Each clinical evidence statement was classified according to a hierarchy. Recommendations were then graded A to C based on the level of associated evidence, or as a good practice point (GPP). All evidence statements and associated forest plots are presented in Appendices 16 and 15 respectively of the original guideline document, while a subset of the key evidence statements are presented in the relevant chapters for ease of reference.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Recommendation Grades

Grade A - At least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (evidence levels I) without extrapolation

Grade B - Well-conducted clinical studies but no randomised clinical trials on the topic of recommendation (evidence levels II or III); or extrapolated from level I evidence

Grade C - Expert committee reports or opinions and/or clinical experiences of respected authorities (evidence level IV) or extrapolated from level I or II evidence. This grading indicates that directly applicable clinical studies of good quality are absent or not readily available

Good practice point (GPP) - Recommended good practice based on the clinical experience of the Guideline Development Group (GDG)

COST ANALYSIS

Health Economics Review Strategies

A systematic review for health economic evidence was conducted. The aim was threefold:

- to identify all publications with information about the economic burden of post-traumatic stress disorder (PTSD) in the UK
- to identify existing economic evaluations of any psychological or pharmacological interventions for the treatment of PTSD undertaken in the UK
- to find studies with health state utility evidence generalisable to the UK context to facilitate a possible cost-utility modelling process.

Although no attempt was made to review systematically studies with only resource use or cost data, relevant UK-based information was extracted for future modelling exercises if it was considered appropriate.

Selection Criteria

Cost-of-illness/economic burden studies:

- no restriction was placed on language or publication status of the papers
- studies published between 1980 and 2003 were included (this date restriction was imposed in order to obtain data relevant to current healthcare settings and costs)
- only studies from the UK were included, as the aim of the review was to identify economic burden information relevant to the national context
- selection criteria based on types of clinical conditions and patients were identical to the clinical literature review (see Appendix 7 of the original guideline document)
- studies were included provided sufficient details regarding methods and results were available to enable the methodological quality of the study to be assessed and provided the study's data and results were extractable.

Economic evaluations:

- studies were included provided they had used cost-minimisation analysis, cost-effectiveness analysis, cost-utility analysis or cost-benefit analysis

- only clinical evidence from a meta-analysis, a randomised controlled trial, a quasiexperimental trial or a cohort study was used
- no restriction was placed on language or publication status of the papers
- studies published between 1980 and 2003 were included (this date restriction was imposed in order to obtain data relevant to current healthcare settings and costs)
- only studies from the UK were considered, as the aim of the review was to identify economic evaluation information relevant to the national context
- selection criteria based on types of clinical conditions, patients, treatments and settings were identical to the clinical literature review (see Appendix 7 of the original guideline document)
- studies were included provided sufficient details regarding methods and results were available to enable the methodological quality of the study to be assessed and provided the study's data and results were extractable.

Health state utility studies:

- studies reporting health state utilities for PTSD were considered for inclusion
- no restriction was placed on language or publication status of the papers
- studies published between 1980 and 2003 were included
- only studies from Organization for Economic Cooperation and Development countries were considered, to assure the generalisability of the results to the UK context
- selection criteria based on types of clinical conditions, patients, treatments and settings were identical to the clinical literature review (see Appendix 7 of the original guideline document).

Data Extraction

Data were extracted by the health economist. Masked assessment, whereby data extractors are masked to the details of journal, authors and so on was not undertaken, because the evidence does not support the claim that this minimises bias.

Details of the findings of the health economic analyses are provided in the original guideline document.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The first draft of the guideline (The full guideline, National Institute for Health and Clinical Excellence (NICE) guideline and Quick Reference Guide) were consulted with Stakeholders and comments were considered by the Guideline Development Group (GDG).

The final consultation draft of the Full guideline, the NICE guideline and the Information for the Public were submitted to stakeholders for final comments.

The final draft was submitted to the Guideline Review Panel for review prior to publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Levels of evidence (I-IV) and grading of recommendations (A-D, GPP) are defined at the end of the Major Recommendations field.

Recognition of Post-traumatic Stress Disorder (PTSD)

Effective treatment of PTSD can only take place if the disorder is recognised. In some cases, for example following a major disaster, specific arrangements to screen people at risk may be considered. For the vast majority of people with PTSD, opportunities for recognition and identification come as part of routine healthcare interventions, for example, following an assault or an accident for which physical treatment is required, or when a person discloses domestic violence or a history of childhood sexual abuse. Identification of PTSD in children presents particular problems but is improved if children are asked directly about their experiences.

Recognition in Primary Care

PTSD can present with a range of symptoms, which in most adults are most commonly in the form of very vivid, distressing memories of the event or flashbacks (otherwise known as intrusive or re-experiencing symptoms). However, at times the most prominent symptoms may be avoidance of trauma-related situations or general social contacts. It is important when recognising and identifying PTSD to ask specific questions in a sensitive manner about both the symptoms and traumatic experiences. A number of problems such as depression are often comorbid with PTSD. Often these problems will improve with the treatment of the PTSD, but where this does not happen or the comorbid disorder impedes the effective treatment of the PTSD, it may be appropriate to consider providing specific treatment for that disorder.

GPP - PTSD may present with a range of symptoms (including re-experiencing, avoidance, hyperarousal, depression, emotional numbing, drug or alcohol misuse and anger) and therefore, when assessing for PTSD, members of the primary care team should ask in a sensitive manner whether or not patients with such symptoms have suffered a traumatic experience (which may have occurred many months or years before) and give specific examples of traumatic events (for example, assaults, rape, road traffic accidents, childhood sexual abuse and traumatic childbirth).

GPP - General practitioners and other members of the primary care team should be aware of traumas associated with the development of PTSD. These include single events such as assaults or road traffic accidents, and domestic violence and childhood sexual abuse.

GPP - For patients with unexplained physical symptoms who are repeated attendees to primary care, members of the primary care team should consider asking whether or not they have experienced a traumatic event, and provide specific examples of traumatic events (for example, assaults, rape, road traffic accidents, childhood sexual abuse and traumatic childbirth).

C - When seeking to identify PTSD, members of the primary care team should consider asking adults specific questions about re-experiencing (including flashbacks and nightmares) or hyperarousal (including an exaggerated startle response or sleep disturbance). For children, particularly younger children, consideration should be given to asking the child and/or the parents about sleep disturbance or significant changes in sleeping patterns.

Recognition in General Hospital Settings

Many people attending for medical services in a general hospital setting may have experienced traumatic events. This may be particularly so in emergency departments and in orthopaedic and plastic surgery clinics. For some people with PTSD, this may be the main point of contact with the healthcare system and the opportunity that this presents for the recognition and identification of PTSD should be taken.

GPP - PTSD may present with a range of symptoms (including re-experiencing, avoidance, hyperarousal, depression, emotional numbing and anger) and therefore when assessing for PTSD, members of secondary care medical teams should ask in a sensitive manner whether or not patients with such symptoms have suffered a traumatic experience and give specific examples of traumatic events (for example, assaults, rape, road traffic accidents, childhood sexual abuse and traumatic childbirth).

Screening of Individuals Involved in a Major Disaster, Programme Refugees and Asylum Seekers

Many individuals involved in a major disaster will suffer both short- and long-term consequences of their involvement. Although the development of single-session debriefing is not recommended, screening of all individuals should be considered by the authorities responsible for developing the local disaster plan. Similarly, the vast majority of programme refugees (people who are brought to the UK from a conflict zone through a programme organised by an agency such as the United Nations High Commission for Refugees) will have experienced major trauma and may benefit from a screening programme.

C - For individuals at high risk of developing PTSD following a major disaster, consideration should be given (by those responsible for coordination of the disaster plan) to the routine use of a brief screening instrument for PTSD at 1 month after the disaster.

C - For programme refugees and asylum seekers at high risk of developing PTSD, consideration should be given (by those responsible for management of the refugee programme) to the routine use of a brief screening instrument for PTSD as part of the initial refugee healthcare assessment. This should be a part of any comprehensive physical and mental health screen.

Specific Recognition Issues for Children

Children, particularly those aged under 8 years, may not complain directly of PTSD symptoms such as re-experiencing or avoidance. Instead, children may complain of sleeping problems. It is therefore vital that all opportunities for identifying PTSD in children should be taken. Questioning the children as well as parents or guardians will also improve the recognition of PTSD. PTSD is common (up to 30%) in children following attendance at emergency departments for a traumatic injury. Emergency department staff should inform parents or guardians of the risk of their child developing PTSD following emergency attendance for a traumatic injury and advise them on what action to take if symptoms develop.

GPP - When assessing a child or young person for PTSD, healthcare professionals should ensure that they separately and directly question the child or young person about the presence of PTSD symptoms. They should not rely solely on information from the parent or guardian in any assessment.

GPP - When a child who has been involved in a traumatic event is treated in an emergency department, emergency staff should inform the parents or guardians of the possibility of the development of PTSD, briefly describe the possible symptoms (for example, sleep disturbance, nightmares, difficulty concentrating and irritability) and suggest that they contact their general practitioner if the symptoms persist beyond 1 month.

Assessment and Coordination of Care

C - For PTSD sufferers presenting in primary care, General Practitioners (GPs) should take responsibility for the initial assessment and the initial coordination of care. This includes the determination of the need for emergency medical or psychiatric assessment.

GPP - Assessment of PTSD sufferers should be conducted by competent individuals and be comprehensive, including physical, psychological and social needs and a risk assessment.

C - Patient preference should be an important determinant of the choice among effective treatments. PTSD sufferers should be given sufficient information about the nature of these treatments to make an informed choice.

C - Where management is shared between primary and secondary care, there should be clear agreement among individual healthcare professionals about the responsibility for monitoring patients with PTSD. This agreement should be in writing (where appropriate, using the Care Programme Approach) and should be shared with the patient and, where appropriate, their family and carers.

Support for Families and Carers

Families and carers have a central role in supporting people with PTSD. However, depending on the nature of the trauma and its consequences, many families may also need support for themselves. Healthcare professionals should be aware of the impact of PTSD on the whole family.

GPP - In all cases of PTSD, healthcare professionals should consider the impact of the traumatic event on all family members and, when appropriate, assess this impact and consider providing appropriate support.

GPP - Healthcare professionals should ensure, where appropriate and with the consent of the PTSD sufferer where necessary, that the families of PTSD sufferers are fully informed about common reactions to traumatic events, including the symptoms of PTSD and its course and treatment.

GPP - In addition to the provision of information, families and carers should be informed of self-help groups and support groups and encouraged to participate in such groups where they exist.

GPP - When a family is affected by a traumatic event, more than one family member may suffer from PTSD. If this is the case, healthcare professionals should ensure that the treatment of all family members is effectively coordinated.

Practical Support and Social Factors

Practical and social support can play an important part in facilitating a person's recovery from PTSD, particularly immediately after the trauma. Healthcare professionals should be aware of this and advocate for such support when people present with PTSD.

GPP - Healthcare professionals should identify the need for appropriate information about the range of emotional responses that may develop and provide practical advice on how to access appropriate services for these problems. They should also identify the need for social support and advocate the meeting of this need.

GPP - Healthcare professionals should consider offering help or advice to PTSD sufferers or relevant others on how continuing threats related to the traumatic event may be alleviated or removed.

Language and Culture

People with PTSD treated in the National Health Service (NHS) come from diverse cultural and ethnic backgrounds and some have no or limited English, but all should be offered the opportunity to benefit from psychological interventions. This can be achieved by the use of interpreters and bicultural therapists. In all cases, healthcare professionals must familiarise themselves with the cultural background of the sufferer.

GPP - Where a PTSD sufferer has a different cultural or ethnic background from that of the healthcare professionals who are providing care, the healthcare professionals should familiarise themselves with the cultural background of the PTSD sufferer.

GPP - Where differences of language or culture exist between healthcare professionals and PTSD sufferers, this should not be an obstacle to the provision of effective trauma-focused psychological interventions.

GPP - Where language or culture differences present challenges to the use of trauma-focused psychological interventions in PTSD, healthcare professionals should consider the use of interpreters and bicultural therapists.

GPP - Healthcare professionals should pay particular attention to the identification of individuals with PTSD where the culture of the working or living environment is resistant to recognition of the psychological consequences of trauma.

Care for All People with PTSD

PTSD responds to a variety of effective treatments. All treatment should be supported by appropriate information to sufferers about the likely course of such treatment. A number of factors, which are described below, may modify the nature, timing and course of treatment.

Care Across All Conditions

GPP - When developing and agreeing a treatment plan with a PTSD sufferer, healthcare professionals should ensure that sufferers receive information about common reactions to traumatic events, including the symptoms of PTSD and its course and treatment.

C - Healthcare professionals should not delay or withhold treatment for PTSD because of court proceedings or applications for compensation.

C - Healthcare professionals should be aware that many PTSD sufferers are anxious about and can avoid engaging in treatment. Healthcare professionals should also recognize the challenges that this presents and respond appropriately, for example by following up PTSD sufferers who miss scheduled appointments.

GPP - Healthcare professionals should treat PTSD sufferers with respect, trust and understanding, and keep technical language to a minimum.

GPP - Healthcare professionals should normally only consider providing trauma-focused psychological treatment when the sufferer considers it safe to proceed.

C - Treatment should be delivered by competent individuals who have received appropriate training. These individuals should receive appropriate supervision.

Comorbidities

C - When a patient presents with PTSD and depression, healthcare professionals should consider treating the PTSD first, as the depression will often improve with successful treatment of the PTSD.

C - For PTSD sufferers whose assessment identifies a high risk of suicide or harm to others, healthcare professionals should first concentrate on management of this risk.

C - For PTSD sufferers who are so severely depressed that this makes initial psychological treatment of PTSD very difficult (for example, as evidenced by

extreme lack of energy and concentration, inactivity, or high suicide risk), healthcare professionals should treat the depression first.

C - For PTSD sufferers with drug or alcohol dependence or in whom alcohol or drug use may significantly interfere with effective treatment, healthcare professionals should treat the drug or alcohol problem first.

C - When offering trauma-focused psychological interventions to PTSD sufferers with comorbid personality disorder, healthcare professionals should consider extending the duration of treatment.

C - People who have lost a close friend or relative due to an unnatural or sudden death should be assessed for PTSD and traumatic grief. In most cases, healthcare professionals should treat the PTSD first without avoiding discussion of the grief.

Treatment of PTSD

Early Interventions

A number of sufferers with PTSD may recover with no or limited interventions. However, without effective treatment, many people may develop chronic problems over many years. The severity of the initial traumatic response is a reasonable indicator of the need for early intervention, and treatment should not be withheld in such circumstances.

Watchful Waiting

C - Where symptoms are mild and have been present for less than 4 weeks after the trauma, watchful waiting, as a way of managing the difficulties presented by individual sufferers, should be considered by healthcare professionals. A follow-up contact should be arranged within 1 month.

Immediate Psychological Interventions for All

As described in this guideline, practical support delivered in an empathetic manner is important in promoting recovery for PTSD, but it is unlikely that a single session of a psychological intervention will be helpful.

GPP - All health and social care workers should be aware of the psychological impact of traumatic incidents in their immediate post-incident care of survivors and offer practical, social and emotional support to those involved.

A - For individuals who have experienced a traumatic event, the systematic provision to that individual alone of brief, single-session interventions (often referred to as debriefing) that focus on the traumatic incident should not be routine practice when delivering services.

PTSD where Symptoms are Present Within 3 Months of a Trauma

Brief psychological interventions (five sessions) may be effective if treatment starts within the first month after the traumatic event. Beyond the first month, the duration of treatment is similar to that for chronic PTSD.

B - Trauma-focused cognitive-behavioural therapy should be offered to those with severe post-traumatic symptoms or with severe PTSD in the first month after the traumatic event. These treatments should normally be provided on an individual out-patient basis.

A - Trauma-focused CBT should be offered to people who present with PTSD within 3 months of a traumatic event.

B - The duration of the trauma-focused CBT should normally be 8-12 sessions, but if the treatment starts in the first month after the event, fewer sessions (about 5) may be sufficient. When the trauma is discussed in the treatment session, longer sessions (for example, 90 min) are usually necessary. Treatment should be regular and continuous (usually at least once a week) and should be delivered by the same person.

C - Drug treatment may be considered in the acute phase of PTSD for the management of sleep disturbance. In this case, hypnotic medication may be appropriate for short-term use but, if longer-term drug treatment is required, consideration should also be given to the use of suitable antidepressants at an early stage in order to reduce the later risk of dependence.

B - Non-trauma-focused interventions such as relaxation or non-directive therapy, which do not address traumatic memories, should not routinely be offered to people who present with PTSD symptoms within 3 months of a traumatic event.

PTSD Where Symptoms Have Been Present For More Than 3 Months After a Trauma

Most patients presenting with PTSD have had the problem for many months, if not years. The interventions outlined below are effective in treating such individuals and duration of the disorder does not itself seem an impediment to benefiting from effective treatment provided by competent healthcare professionals.

Psychological Interventions

A - All PTSD sufferers should be offered a course of trauma-focused psychological treatment (trauma-focused CBT or eye movement desensitisation and reprocessing). These treatments should normally be provided on an individual out-patient basis.

B - Trauma-focused psychological treatment should be offered to PTSD sufferers regardless of the time that has elapsed since the trauma.

B - The duration of trauma-focused psychological treatment should normally be 8-12 sessions when the PTSD results from a single event. When the trauma is discussed in the treatment session, longer sessions than usual are generally

necessary (for example, 90 min). Treatment should be regular and continuous (usually at least once a week) and should be delivered by the same person.

C - Healthcare professionals should consider extending the duration of treatment beyond 12 sessions if several problems need to be addressed in the treatment of PTSD sufferers, particularly after multiple traumatic events, traumatic bereavement or where chronic disability resulting from the trauma, significant comorbid disorders or social problems are present. Trauma-focused treatment needs to be integrated into an overall plan of care.

C - For some PTSD sufferers it may initially be very difficult and overwhelming to disclose details of their traumatic events. In these cases, healthcare professionals should consider devoting several sessions to establishing a trusting therapeutic relationship and emotional stabilisation before addressing the traumatic event.

B - Non-trauma-focused interventions such as relaxation or non-directive therapy, which do not address traumatic memories, should not routinely be offered to people who present with chronic PTSD.

C - For PTSD sufferers who have no or only limited improvement with a specific trauma-focused psychological treatment, healthcare professionals should consider the following options:

- an alternative form of trauma-focused psychological treatment
- the augmentation of trauma-focused psychological treatment with a course of pharmacological treatment.

GPP - When PTSD sufferers request other forms of psychological treatment (for example, supportive therapy/non-directive therapy, hypnotherapy, psychodynamic therapy or systemic psychotherapy), they should be informed that there is as yet no convincing evidence for a clinically important effect of these treatments on PTSD.

Drug Treatment

The evidence base for drug treatments in PTSD is limited. There is evidence of clinically significant benefits for mirtazapine, amitriptyline and phenelzine. (Dietary guidance is required with phenelzine.) For paroxetine there were statistically but not clinically significant benefits on the main outcome variables. Nevertheless, this drug has also been included in the list of recommended drugs. This is the only drug in the list of recommendations with a current UK product licence for PTSD.

A - Drug treatments for PTSD should not be used as a routine first-line treatment for adults (in general use or by specialist mental health professionals) in preference to a trauma-focused psychological therapy.

B - Drug treatments (paroxetine or mirtazapine for general use, and amitriptyline or phenelzine for initiation only by mental health specialists) should be considered for the treatment of PTSD in adults where a sufferer expresses a preference not to engage in a trauma-focused psychological treatment.

C - Drug treatments (paroxetine or mirtazapine for general use, and amitriptyline or phenelzine for initiation only by mental health specialists) should be offered to adult PTSD sufferers who cannot start a psychological therapy because of serious ongoing threat of further trauma (for example, where there is ongoing domestic violence).

C - Drug treatments (paroxetine or mirtazapine for general use and amitriptyline or phenelzine for initiation only by mental health specialists) should be considered for adult PTSD sufferers who have gained little or no benefit from a course of trauma-focused psychological treatment.

C - Where sleep is a major problem for an adult PTSD sufferer, hypnotic medication may be appropriate for short-term use but, if longer-term drug treatment is required, consideration should also be given to the use of suitable antidepressants at an early stage in order to reduce the later risk of dependence.

C - Drug treatments (paroxetine or mirtazapine for general use and amitriptyline or phenelzine for initiation only by mental health specialists) for PTSD should be considered as an adjunct to psychological treatment in adults where there is significant comorbid depression or severe hyperarousal that significantly impacts on a sufferer's ability to benefit from psychological treatment.

C - When an adult sufferer with PTSD has not responded to a drug treatment, consideration should be given to increasing the dosage within approved limits. If further drug treatment is considered, this should generally be with a different class of antidepressant or involve the use of adjunctive olanzapine.

C - When an adult sufferer with PTSD has responded to drug treatment, it should be continued for at least 12 months before gradual withdrawal.

General Recommendations Regarding Drug Treatment

C - All PTSD sufferers who are prescribed antidepressants should be informed, at the time that treatment is initiated, of potential side-effects and discontinuation/withdrawal symptoms (particularly with paroxetine).

GPP - Adult PTSD sufferers started on antidepressants who are considered to have an increased suicide risk and all patients aged between 18 and 29 years (because of the potential increased risk of suicidal thoughts associated with the use of antidepressants in this age group) should normally be seen after 1 week and frequently thereafter until the risk is no longer considered significant.

GPP - Particularly in the initial stages of SSRI treatment, practitioners should actively seek out signs of akathisia, suicidal ideation and increased anxiety and agitation. They should also advise PTSD sufferers of the risk of these symptoms in the early stages of treatment and advise them to seek help promptly if these are at all distressing.

GPP - If a PTSD sufferer develops marked and/or prolonged akathisia while taking an antidepressant, the use of the drug should be reviewed.

GPP - Adult PTSD sufferers started on antidepressants who are not considered to be at increased risk of suicide should normally be seen after 2 weeks and thereafter on an appropriate and regular basis, for example, at intervals of 2-4 weeks in the first 3 months, and at greater intervals thereafter, if response is good.

Recommendations Regarding Discontinuation/Withdrawal Symptoms

C - Discontinuation/withdrawal symptoms are usually mild and self-limiting but occasionally can be severe. Prescribers should normally gradually reduce the dosage of antidepressants over a 4-week period, although some people may require longer periods.

C - If discontinuation/withdrawal symptoms are mild, practitioners should reassure the PTSD sufferer and arrange for monitoring. If symptoms are severe, the practitioner should consider reintroducing the original antidepressant (or another with a longer half-life from the same class) and reduce gradually while monitoring symptoms.

Chronic Disease Management

C - Chronic disease management models should be considered for the management of people with chronic PTSD who have not benefited from a number of courses of evidence-based treatment.

Children

It is particularly difficult to identify PTSD in children (see section above titled "Specific Recognition Issues for Children"). The treatments for children with PTSD are less developed but emerging evidence provides an indication for effective interventions.

Early Intervention

B - Trauma-focused CBT should be offered to older children with severe post-traumatic symptoms or with severe PTSD in the first month after the traumatic event.

PTSD Where Symptoms Have Been Present for More Than 3 Months After a Trauma

B - Children and young people with PTSD, including those who have been sexually abused, should be offered a course of trauma-focused CBT adapted appropriately to suit their age, circumstances and level of development.

C - The duration of trauma-focused psychological treatment for children and young people with chronic PTSD should normally be 8–12 sessions when the PTSD results from a single event. When the trauma is discussed in the treatment session, longer sessions than usual are usually necessary (for example, 90 min). Treatment should be regular and continuous (usually at least once a week) and should be delivered by the same person.

C - Drug treatments should not be routinely prescribed for children and young people with PTSD.

C - Where appropriate, families should be involved in the treatment of PTSD in children and young people. However, treatment programmes for PTSD in children and young people that consist of parental involvement alone are unlikely to be of any benefit for PTSD symptoms.

C - When considering treatments for PTSD, parents and, where appropriate, children and young people should be informed that, apart from trauma-focused psychological interventions, there is at present no good evidence for the efficacy of widely used forms of treatment of PTSD such as play therapy, art therapy or family therapy.

Disaster Planning

Both health and social services have a role in organising the appropriate social and psychological support for those affected by disasters.

GPP - Disaster plans should include provision for a fully coordinated psychosocial response to the disaster. Those responsible for developing the psychosocial aspect of a disaster plan should ensure it contains the following: provision for immediate practical help, means to support the affected communities in caring for those involved in the disaster and the provision of specialist mental health, evidence based assessment and treatment services. All healthcare workers involved in a disaster plan should have clear roles and responsibilities, which should be agreed in advance.

Definitions

Levels of Evidence

I: Evidence obtained from a single randomised controlled trial or a meta-analysis of randomised controlled trials

IIa: Evidence obtained from at least one well-designed controlled study without randomisation

IIb: Evidence obtained from at least one other well-designed quasi-experimental study

III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, and case studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities.

Grading of Recommendation

Grade A - At least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (evidence levels I) without extrapolation

Grade B - Well-conducted clinical studies but no randomised clinical trials on the topic of recommendation (evidence levels II or III); or extrapolated from level I evidence

Grade C - Expert committee reports or opinions and/or clinical experiences of respected authorities (evidence level IV) or extrapolated from level I or II evidence. This grading indicates that directly applicable clinical studies of good quality are absent or not readily available.

Good practice point (GPP) - Recommended good practice based on the clinical experience of the Guideline Development Group (GDG)

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Consistent and improved quality of care and outcomes for people with post traumatic stress disorder

POTENTIAL HARMS

- Side effects of paroxetine may include anxiety, agitation, suicidal thoughts and akathisia.
- Dietary restrictions and careful monitoring are required for patients taking monoamine oxidase inhibitors.
- Medication discontinuation/withdrawal symptoms may occur.
- Administration of some drugs to nursing mothers may lead to effects in breastfeeding infants.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Health professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of health professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation in the National Health Service (NHS)

In General

Local health communities should review their existing practice in the treatment and management of post-traumatic stress disorder (PTSD) against this guideline. The review should consider the resources required to implement the recommendations set out in Section 1 of the original guideline document (short version) and in the "Major Recommendations" section of this summary, the people and processes involved and the timeline over which full implementation is envisaged. It is in the interests of PTSD sufferers that the implementation timeline is as rapid as possible.

Relevant local clinical guidelines, care pathways and protocols should be reviewed in the light of this guidance and revised accordingly.

This guideline should be used in conjunction with the National Service Framework for Mental Health, which is available from www.dh.gov.uk.

Audit

Suggested audit criteria are listed below and in Appendix D of the short version of the original guideline document. These can be used as the basis for local clinical audit, at the discretion of those in practice.

Possible Objectives for an Audit

One or more audits could be carried out in different care settings to ensure that:

- individuals with PTSD are involved in their care
- treatment options, including psychological interventions, are appropriately offered and provided for individuals with PTSD.

People Who Could be Included in an Audit

A single audit could include all individuals with PTSD. Alternatively, individual audits could be undertaken on specific groups of individuals such as:

- people with a specific type of PTSD (for example, to study early intervention)

- a sample of patients from particular populations in primary care.

Measures That Could be Used as a Basis for an Audit

Please see tables in Appendix D of the original guideline document.

IMPLEMENTATION TOOLS

Patient Resources
Quick Reference Guides/Physician Guides
Slide Presentation

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Mental Health. Post-traumatic stress disorder: the management of PTSD in adults and children in primary and secondary care. London (UK): National Institute for Clinical Excellence (NICE); 2005. 167 p. [69 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005

GUIDELINE DEVELOPER(S)

National Collaborating Centre for Mental Health - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Guideline Development Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

At each Guideline Development Group (GDG) meeting, all GDG members declared any potential conflict of interests.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format [PDF] format from the National Institute for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- National Collaborating Centre for Mental Health. Post-traumatic stress disorder (PTSD). The management of PTSD in adults and children in primary and secondary care. NICE guideline (Clinical guideline 26). London (UK): National Institute for Health and Clinical Excellence (NICE); 2005 Mar. 41 p. Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- National Collaborating Centre for Mental Health. Post-traumatic stress disorder (PTSD). The management of PTSD in adults and children in primary and secondary care. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2005 Mar. 17 p. Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- Post-traumatic stress disorder--presenter slides. Available from the NICE Web site.

PATIENT RESOURCES

The following is available:

- Post-traumatic stress disorder (PTSD): the treatment of PTSD in adults and children. Understanding NICE guidance – information for people with PTSD, their advocates and carers, and the public. National Institute for Health and Clinical Excellence (NICE), 2005 Mar. 36 p. Available in Portable Document Format (PDF) from the National Institute for Clinical Excellence (NICE) Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455, ref N0849.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on May 4, 2005. The information was verified by the guideline developer on February 8, 2006. This summary was updated by ECRI on May 31, 2006 following the U.S. Food and Drug Administration advisory on Paxil (paroxetine hydrochloride).

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